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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/254,152    02/26/99    HIGASHIYAMA

K    001560-344

EXAMINER

WANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/23/00

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HM22/0323

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/254,152

Applicant(s)

HIGASHIYAMA ET AL

Examiner

Sh ngjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1,2,4-11 and 13-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11 and 13-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
3. ☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.

- 17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: \_\_\_\_.

Art Unit: 1617

## DETAILED ACTION

### *Claim Rejection 35 USC – 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 14 recites the broad recitation "a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of 35 % or less," and the claim also recites "a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio in a proportion of 0.14 or less with respect to desmosterol composition ratio" (this can be translate into a 24,25-methylenecholest-5-

Art Unit: 1617

en-3 $\beta$ -ol compositional ratio of 13 % or less) which is the narrower statement of the range/limitation.

***Claim Rejection 35 USC - 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4-11 and 19-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shinmen et al. and Shimizu et al.

Shinmen et al. teach a process for production of an unsaturated fatty acid-containing oil comprising culturing with aeration a microorganism belonging to the genus *Mortierella* subgenus *Mortierella* in a liquid medium containing a nitrogen source and collecting the unsaturated fatty acid-containing oil from the cultured product. See, particularly, the summary on page 11 and page 15, the left column. The nitrogen source can be a defatted soybean product, e.g., soybean meal. See, particularly, page 14, left column, the second paragraph. The unsaturated fatty acid-containing oil contains about 18-60 % of arachidonic acid. See, particularly, Fig 3 on page 15. Shinmen et al. do not disclose 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio or the proportion of 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio with respect to desmosterol composition ratio. However, Shimizu et al. teach that an unsaturated fatty acid-containing oil obtained from a process similar to the process of Shinmen et al. has a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of 21 % and 24,25-methylenecholest-5-

Art Unit: 1617

en-3 $\beta$ -ol compositional ratio in a proportion of 0.37 with respect to desmosterol composition ratio. See, page 482, table 1. Therefore, properties such as having a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of 35 % or less and 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio in a proportion of 1.2 or less with respect to desmosterol composition ratio are considered inherent properties of the unsaturated fatty acid-containing oil of Shinmen et al.

***Claim Rejection 35 USC – 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 13-18 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinmen et al in view of both of Shimizu et al and Barclay.

Shinmen et al. teach a unsaturated fatty acid-containing oil obtained from culturing of microorganism *Mortierella* contains about 18-60 % of arachidonic acid. See, particularly, Fig 3 on page 15. Shinmen also teach the nutritive effect of arachidonic acid. See, particularly, the introduction on page 11.

Shinmen et al. do not teach how much of 24,25-methylenecholest-5-en-3 $\beta$ -ol is present in the oil. Shinmen do not teach the employment of such oil in food products including baby food and animal food.

Art Unit: 1617

However, Shimizu et al. teach that unsaturated fatty acid-containing oil obtained from culturing microorganism *Mortierella* has 24,25-methylenecholest-5-en-3 $\beta$ -ol which has not been found in nature, i.e., not found in any natural food such as breast milk and its biological activity and toxicity have not been fully evaluated. See, particularly, the abstract on page 481. Barclay teach the employment of arachidonic acid containing oil obtained from culturing microorganism *Mortierella* for food product including baby food and animal food. See, particularly, column 7, line 48-60.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to modify the unsaturated fatty acid-containing oil of Shinmen et al. by removing the biologically unknown compound, i.e., 24,25-methylenecholest-5-en-3 $\beta$ -ol and employ the modified oil in food products such as baby food and animal food or in nutritive dietary supplement.

A person of ordinary skill in the art would have been motivated to remove 24,25-methylenecholest-5-en-3 $\beta$ -ol from the unsaturated fatty acid-containing oil and employ the modified oil in food products such as baby food and animal food or in nutritive dietary supplement because the biological activity of 24,25-methylenecholest-5-en-3 $\beta$ -ol is not known and it would not be safe to use such oil in baby food. Methods of removing the compound such as chromatography separation or modification of fermentation conditions are considered within the skill of artisan. Furthermore, employment of unsaturated fatty acid-containing oil in food products are known.

Art Unit: 1617

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

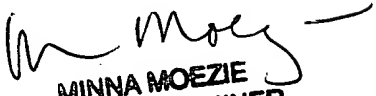
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shengjun Wang

AU 1617

March 18, 2000

  
MINNA MOEZIE  
PRIMARY EXAMINER